

**STOOL SOFTENER LAXATIVE- docusate sodium capsule  
REMEDYREPACK INC.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

**Active ingredient (in each softgel)**

Docusate Sodium 100 mg

**Purpose**

Stool softener laxative

**Uses**

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

**Warnings**

**Do not use**

if you are presently taking mineral oil, unless told to do so by a doctor.

**Ask a doctor before use if you have**

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last over 2 weeks

**Stop use and ask a doctor if**

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be a signs of a serious condition.
- you need to use a laxative for more than 1 week

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

## Directions

- take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over	take 1 to 3 softgels daily.
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

## Other information

- **each softgel contains:** sodium 5 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

## Inactive ingredients

edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water sorbitan, sorbitol

## Questions or comments?

Call **1-800-616-2471**

## PRINCIPAL DISPLAY PANEL

DRUG: Docusate Sodium

GENERIC: DOCUSATE SODIUM

DOSAGE: CAPSULE

ADMINISTRATION: ORAL

NDC: 70518-3049-0

NDC: 70518-3049-1

COLOR: orange

SHAPE: OVAL

SCORE: No score

SIZE: 12 mm

IMPRINT: P51

PACKAGING: 30 in 1 BLISTER PACK

PACKAGING: 7 in 1 BLISTER PACK

ACTIVE INGREDIENT(S):

- DOCUSATE SODIUM 100mg in 1

INACTIVE INGREDIENT(S):

- FD&C RED NO. 40

- FD&C YELLOW NO. 6
- GELATIN
- SORBITAN
- POLYETHYLENE GLYCOL, UNSPECIFIED
- PROPYLENE GLYCOL
- WATER
- SORBITOL
- GLYCERIN
- MEDIUM-CHAIN TRIGLYCERIDES

# Docosate Sodium

Stool Softener Laxative

**100 mg**

**Capsule**

**QTY: 30 Capsules**



**NOT FOR RETAIL SALE**

NDC #: 70518-3049-00

Expires:

LOT #:

Source NDC: 00904-6998-80

MFG: Major Pharma, Livonia, MI 48152

Keep this and all medication out of the reach of children



Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762

## STOOL SOFTENER LAXATIVE

docosate sodium capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70518-3049(NDC:0904-6998)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	P51
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518-3049-0	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	03/17/2021	
2	NDC:70518-3049-1	7 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/09/2021	08/05/2021

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/17/2021	

**Labeler** - REMEDYREPACK INC. (829572556)

Revised: 9/2022

REMEDYREPACK INC.